DEPARTMENT OF HEALTH AND HUMAN SERVICES

gf 42184

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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August 14, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-38

Frank D. Dulcich, President
Pacific Seafood Group
3220 SW First Avenue
Portland, Oregon 97201

WARNING LETTER

Dear Mr. Dulcich:

On June 2-4, 2003, we inspected your firm, Washington Crab Producers Inc., 1980 North Nyhus, Westport, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342 (a)(4). Accordingly your cooked dungeness crabmeat and whole crab distributed in vacuum-pulled metal cans, and in reduced oxygen plastic tubs, are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find this Act, the Seafood HACCP regulation, and the FDA Fish and Fisheries Products Hazards and Controls Guidance through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." Your firm's HACCP plan for dungeness crabmeat in cans, and in reduced oxygen plastic tubs does not list the food safety hazard of *Clostridium botulinum*, during

finished product storage and distribution, which FDA considers to be a food safety hazard that is reasonably likely to occur.

Please note that information regarding the control of *Clostridium botulinum* in vacuum-packaged, and reduced oxygen packaged seafood products can be found in the Fish and Fisheries Products and Hazards Guidance: Third Edition, Chapter 13.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cooked dungeness crab lists a critical limit, "minimum temperature internal [redacted]°F," that is inadequate to control pathogen survival.

   FDA does not consider measuring internal temperatures an appropriate method to assure that all of the crabs in each batch have been adequately cooked to destroy pathogens. Variations in temperatures can occur from crab to crab based on crab size and its location in the cooker. Your critical limit(s) at this critical control point should list the minimum cook temperature and time necessary to achieve a safe cook of all the crabs in the basket. These critical limits should be based on how full the cooker is and the size of the crabs. Internal temperatures may be used as a verification tool to assure that safe internal temperatures have been achieved, but not as a primary assurance of pathogen destruction.

3. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.69(c)(4). However, your firm's HACCP plan for cooked dungeness crab lists a monitoring frequency of [redacted] at the cooking critical control point that is not adequate to control the hazard of pathogen survival.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the prevention of cross-contamination from insanitary objects to food, food packaging materials, and other food contact surfaces including utensils, gloves, and outer garments, and from raw product to cooked product in that the following observations were noted:

   a). Employees were observed to handle various un-sanitized objects such as a pallet jack handle, plastic bags of crab sections, a hose stored on the floor, and an ice shovel handle, and then have direct hand contact with the cooked crab without washing or sanitizing gloved hands.

   b). Employees were observed handling or touching various un-sanitized objects with gloved hands i.e. laminated employee number tags, computer keyboards, buttons on a scale read-out, and then directly handling product without washing hands prior to rinsing them in sanitizer.

Your response of July 18, 2003 does not adequately address the issues in FDA-483 items number 1 and 2 in that the data you submitted was for a one can study which is not representative of all shipments, and as stated above FDA does not consider measuring internal temperatures as appropriate. Your response to FDA-483 item # 3, 4, 5 and 6 appear adequate.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. Please respond in writing within 15 working days from your receipt of this letter. You may wish to include in your response documentation such as your revised HACCP plan, and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal, Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosures:

Form FDA 483

cc: WSDA with disclosure statement

cc: Glen White, General Manager
Washington Crab Producers, Inc.
1980 Nyhus North
Westport, Washington 98595